

List of revisions for the Intramural Clinical Trial Template, Version 2.0, dated October 2007:

- **Section 7.2.2.2:** Updated specimen shipping with new IATA language and US Postal Service Requirements;
- **Section 8:** Added the term "data" to ensure that it applies to specimens, samples and data;
- **Section 8.1:** Added missing language regarding disposition of specimens, samples and data at the termination of the protocol (an oversight);
- **Section 8.1:** Updated Office of Technology Development links (Instructions manual);
- **Section 10.2:** Updated Adverse Event definition and instructions per the Clinical Safety Reporting CROM and the AER Working Group;
- **Section 10.5:** Added a new subsection called "Reporting Procedure for Unanticipated Adverse Device Effects" per 21 CFR 812.3(s);
- **Section 11.2.1:** Updated DSMB language provided by the DSMB CROM;
- **Section 11.2.1:** Updated SMC language provided by the DSMB CROM;
- **Section 13:** Added the definitions of QA/QC as provided by the IRB CROM;
- **Section 16:** Added instructions for the new NIAID pre-publication Clearance for Intramural Manuscripts, (11/06);
- **Instructions Manual:** Fixed numerous broken regulatory links and provided instructions to navigate to various guidance documents located on either the NIAID DCR IRB or RCHSPB web portals, since direct linking is no longer possible;
- **Templates and Instruction Manual:** Fixed typos and minor spacing issues;
- **Templates and Instruction Manual:** Removed the table structure from the "List of Abbreviations" to eliminate a MAC/PC platform issue with tables;
- **Templates and Instruction Manual:** Removed the table structure from "Protocol Summary" to eliminate a MAC/PC platform issue with tables;
- **Templates and Instruction Manual:** Renamed the file names to shorter names, to facilitate clearer downloads in the MAC environment.